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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,136	02/06/2002	David N. Edwards	AP33990 068660.0109	2663

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EXAMINER

SITTON, JEHANNE SOUAYA

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/071,136

Applicant(s)

EDWARDS, DAVID N.

Examiner

Jehanne S. Sitton

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 July 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: none.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.

Attachment

1. The proposed amendment filed 7/20/2005 will not be entered because the proposed changes in claims 1, 25, and 32 to Gal4 “binding domain” common peptide or “at least one Gal4 activation domain” common peptide changes the scope of the claims and requires new search and consideration. Further, such amendment would require a rejection under 112/2nd because it is unclear whether the amendment seeks to limit the claims to either the Gal4 binding domain or the Gal4 activation domain, or to portions of such.

2. Arguments with regard to the instantly pending claims will be addressed.

With regard to the rejection of claims 1-4, 10, 11, 13, and 23-32 under 35 USC 102(a) and 102(e) as being anticipated by Thukral, the response asserts at page 9, that contrary to the examiner’s assertion, it does not necessarily follow that “the GAL4 translation initiation sequence was specifically taught by Thukral to have been removed”; and at page 10, that in PCT Publication No. WO96/40904, cited by Thukral, “5’ untranslated regions are specifically excluded”. These arguments have been thoroughly reviewed but were found unpersuasive. Firstly, Thukral teaches that sequences between the alcohol dehydrogenase promoter and ADH terminator were removed. Since the GAL4 translation initiation sequence is found in between these two elements, Thukral teaches that it was necessarily removed. The attorney’s arguments with regard to alternative reasons which might suggest that the sequence was not necessarily removed cannot take the place of evidence on the record showing that the sequence was not removed. However, this should not be construed as an invitation to provide evidence.

As stated in the MPEP: 716.01 [R-2] (A)

Timeliness:

Evidence traversing rejections must be timely or seasonably filed to be entered and entitled to consideration. In re Rothermel, 276 F.2d 393, 125 USPQ 328

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(CCPA 1960). Affidavits and declarations submitted under 37 CFR 1.132 and other evidence traversing rejections are considered timely if submitted:

- (1) prior to a final rejection,
- (2) before appeal in an application not having a final rejection, or
- (3) after final rejection and submitted
 - (i) with a first reply after final rejection for the purpose of overcoming a new ground of rejection or requirement made in the final rejection, or
 - (ii) with a satisfactory showing under 37 CFR 1.116(b) or 37 CFR 1.195, or
 - (iii) under 37 CFR 1.129(a).

Secondly, contrary to the response's assertion, W096/40904, cited by Thukral, does not specifically exclude 5' untranslated sequences as the disclosure generally discusses selecting for DNA molecules comprising the '5' end of a gene (page 2, lines 28-30), which includes 5' untranslated sequences.

With regard to the rejection of Fields and Thukral under 35 USC 103, the response asserts that Thukral refers to 5' ends which are translated. This argument has been thoroughly reviewed but was found unpersuasive for the reasons made of record above. The response further asserts that there is no suggestion or motivation to combine the teachings of Fields and Thukral and that the combination is improper because it would render the prior art unsatisfactory for its intended purposes, would change the principle of operation of the prior art inventions and the vectors taught independently do not suggest the combination. These arguments are not persuasive. The response relies on specific aspects of each reference and attempts to combine them to show that the combination is improper because it would render the prior art unsatisfactory for its intended purposes and would change the principle of operation of the prior art inventions. However, these specific elements were not used in the rejection. The rejection relied on general teachings and aspects of vector constructs and did not suggest, for example that GAL 4 should be used instead of Thukral's reporter in the construct of Thukral. As noted in

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MPEP 2145, "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.... Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981)." With regard to the arguments at page 14, the rejection did not suggest that the Fields or Thukral construct be modified for the purpose set forth in the response. Arguments and evidence at pages 15-first para page 18, will not be addressed as the combination of Fields and Thukral was set forth in a non final rejection. As stated in MPEP 2145, "The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997)". This should not be construed as an invitation to provide further evidence after the final rejection, see "Timeliness" above. Further, as prosecution on the instant application is closed and applicants have not provided a good and sufficient reason as to why such evidence and arguments were not previously presented, such arguments and evidence will not be addressed.

With regard to arguments made at pages 18 (B) –page 20 (F), such arguments were not found persuasive for the reasons made of record above and in previous office actions.

With regard to arguments made at page 20 (G), rejection of claim 12 as unpatentable over Thukral, such arguments were not found persuasive for reasons made of record above.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Jehanne Sitton
Primary Examiner
Art Unit 1634

8/15/05